

## **REMARKS**

### **FORMAL MATTERS:**

Claims 1, 7-9, 13, and 15-17 are now pending in this application.

Claim 2 was previously canceled. Claims 3-6 are cancelled here as are claims 10-12. Claim 14 was previously canceled. Claims 18 and 19 are canceled here. Claims 20-42 were previously canceled. Claims 43-47 are canceled here.

Claim 1 is amended to incorporate limitations contained within previously pending now canceled claims 5, 6 and 12. Although this is an amendment after final the amendment to claim 1 incorporates limitations contained within previously pending now canceled dependent claims. Thus, these amendments are proper under 37 C.F.R. §1.116 in response to a final Office Action. The amendments to claim 1 along with the cancellation of other claims would narrow any issues on appeal, not require additional searching and as such their entry is respectfully requested.

No new matter has been added.

### **SUMMARY**

The only remaining independent claim which is claim 1 has been amended to incorporate limitations contained within dependent claims 5, 6 and 12. Such an amendment is applicant's right under 37 C.F.R. §1.116. The specific structural limitations added to claim 1 are clearly not shown within Dardik et al. or Saxon. Specifically, there is no showing of the structure with a proximal end that is bifurcated for positioning the free margin of the prolapsing leaflet therein. Further, there is no showing of a structure with a coaptation surface configured to substantially mimic a normally functioning leaflet. There is no teaching towards these features because the cited art does not teach towards applicant's invention which is an implantable device structure which is useful in repairing a regurgitant cardiac valve. Specific structural limitations recited within claim 1 make such a repair possible.

### **ELECTION/RESTRICTION**

The Office Action points out that claims 3, 4, 10 and 11 were withdrawn. These claims are canceled here as are claims 18 and 19. Thus, any issues with respect to these claims have been rendered moot.

**REJECTIONS UNDER 35 U.S.C. §102**

Claims 1, 5, 7-9, 12, 16-19 and 44-47 were rejected under 35 U.S.C. §102(b) as being anticipated by Dardik et al. (US Patent 3,988,782). The rejection is traversed as applied and as it might be applied to the presently pending claims.

The rejection was not applied against dependent claim 6 which claim specifically defined the structure as having a proximal end with a bifurcated configuration for positioning the free margin of the prolapsing leaflet therein. Because the limitations of dependent claim 6 have been included into independent claim 1 the rejection has been rendered moot with respect to amended claim 1 and remaining claims 7-9 as well as claims 16 and 17 which depend directly on claim 1. Claims 12, 18-19 and 44-47 have been canceled. Accordingly, the rejection has been rendered moot with respect to all of the claims 1, 5, 7-9, 12, 16-19 and 44-47.

**REJECTIONS UNDER 35 U.S.C. §102 OVER SAXON**

Claims 1, 5, 6-9, 12, 16-19 and 44-47 were rejected under 35 U.S.C. §102 as anticipated by Saxon. The rejection is traversed as applied and as it might be applied to the presently pending claims. Saxon discloses a prosthesis for the repair of soft tissue defects in general. However, there is no specific teaching towards a structure which could be used in connection with repairing a heart valve. Specifically, the term “heart valve” is not mentioned in the patent. For this reason alone the 35 U.S.C. §102 rejection over the amended claims should be reconsidered and withdrawn.

Two structural features were added to independent claim 1 which is the only remaining independent claim. First, independent claim 1 now specifically indicates that the structure includes a proximal end which is bifurcated for positioning the free margin of the prolapsing leaflet therein. Such is not taught within Saxon. Further, since Saxon says nothing with respect to heart valves Saxon cannot teach a structure with a coaptation surface configured to substantially mimic a normally functioning leaflet as now claimed within amended claim 1. In view of such the rejection should be reconsidered and withdrawn.

### **REJECTIONS UNDER §103(a)**

Claims 13 and 15 were rejected under 35 U.S.C. §103(a) as being unpatentable over Dardik et al. (US Patent 3,988,782). The rejection is traversed as applied and as it might be applied to the presently pending claims.

First, applicants point out that claim 1 has now been amended to incorporate limitations contained within previously pending now canceled claims 5, 6 and 12. Thus, the rejection is not applied against the presently pending versions of claims 13 and 15 which are dependent on the amended claim 1. Thus, in view of the claim amendments reconsideration and withdrawal of the rejection is respectfully requested. In that neither Dardik et al. or Saxon as taken alone or in combination teach an implantable device as claimed specifically with a proximal end which has a bifurcated configuration.

Second, claim 1 now specifically defines the structure as having a coaptation surface configured to substantially mimic a normally functioning leaflet. This language has been added to claim 1 from dependent claim 12 to further define the surface structure. No sure structural parameters are taught within Dardik et al. or Saxon.

### **ADDITIONAL ARGUMENTS**

Applicant recognizes that the Examiner is correct in pointing out that Dardik does refer to a heart valve. However, there is very little reference to a heart valve within Dardik. Specifically, the term is used in claim 51. It also appears at col. 1, line 25 in the "Background of the Invention" section. Lastly, the term appears at col. 8, line 60. This section of the disclosure reads as follows:

"A plurality of segments may be used in certain applications such as for lining the pericardium of the heart, or a heart valve, or for covering an artificial implant such as a pacemaker. Segments may also be used in plastic surgery as an inert reconstructive material." (See col. 8, lines 58-62)

There is no reference to a "heart valve" of any sort within Saxon. Thus, even if the references are combined (and no such combined rejection has been put forth) there is no teaching of an implantable device as claimed. Specifically, there is no teaching of a structure defining a stable coaptation surface

against which an opposing leaflet reversibly coapts” as claimed within claim 1. Further, there is no disclosure of a structure with a “coaptation surface configured to extend freely beyond a free margin of the prolapsing segment when the structure is operatively implanted within the valve” as is also claimed in claim 1.

**Neither Dardik or Saxon as taken alone or in combination teach a structure with a coaptation surface “configured to substantially mimic a normally functioning leaflet” as is also claimed in claim 1.**

**Lastly, neither Dardik or Saxon alone or in combination teach a structure where a proximal end has a bifurcated configuration for positioning the free margin of the prolapsing leaflet therein.**

Applicant has provided an implantable device structure which is useful in repairing a regurgitant cardiac valve. Such is not taught within either of the references. The specific structural limitations now recited within the claims clearly distinguish applicant’s invention from the cited art. In view of such reconsideration and withdrawal is respectfully requested.

#### **CONCLUSION**

In the event the Examiner finds that minor issues remain unresolved the Examiner is respectfully requested to contact the undersigned attorney at the indicated telephone number to expedite the disposition of this application.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number MSSM-001.

Respectfully submitted,  
BOZICEVIC, FIELD & FRANCIS LLP



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By: \_\_\_\_\_

Karl Bozicevic  
Registration No. 28,807

BOZICEVIC, FIELD & FRANCIS LLP  
1900 University Avenue, Suite 200  
East Palo Alto, California 94303  
Telephone: (650) 327-3400  
Facsimile: (650) 327-3231